

# United States Department of Agriculture

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

23226-23300

**23226. Adulteration of elixir sodium salicylate compound; and adulteration and misbranding of fluidextract digitalis, fluidextract jalap, fluidextract nux vomica, fluidextract stramonium, tincture ferric citro-chloride, elixir gentian and iron, syrup hypophosphites compound, and syrup bromides. U. S. v. Nelson, Baker & Co. Plea of guilty. Fine, \$200. (F. & D. no. 30277. Sample nos. 4044-A, 4051-A, 4053-A, 4054-A, 4055-A, 4059-A, 4068-A, 4070-A, 4073-A.)**

This case was based on shipments of various drugs and drug preparations sold under names recognized in the National Formulary. Examination showed that they differed from the standard laid down in the formulary, in most instances containing more, or less, of certain therapeutic agents than declared on the labels.

On April 4, 1934, the United States attorney for the Eastern District of Michigan, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Nelson, Baker & Co., a corporation, Detroit, Mich., alleging shipment by said company in violation of the Food and Drugs Act, on or about July 6, 1932, from the State of Michigan into the State of Illinois, of quantities of pharmaceuticals which were adulterated and, with one exception, also misbranded. The articles were labeled in part: "Fluidextract Digitalis N.F."; "Fluidextract Jalap, N.F."; "Fluidextract Nux Vomica N.F."; "Fluidextract Stramonium, N.F."; "Tincture Ferric Citro-Chloride Alcohol 14 Per Cent"; "Elixir Gentian and Iron N.F.IV"; "Elixir Sodium Salicylate Cpd."; "Syrup Hypophosphites Compound N.F."; "Syrup Bromides N.F."; "Nelson Baker & Co. Detroit, Mich."

The articles were alleged to be adulterated in that they were sold under names recognized in the National Formulary, and differed from the standard of strength, quality, and purity as determined by the tests laid down in the said formulary official at the time of investigation in the following respects and their own standard of strength, quality, and purity was not declared on the containers thereof:

(Fluidextract digitalis) One cubic centimeter of the article corresponded to 0.46 milligram of ouabain, whereas the formulary provides that 1 cubic centimeter of fluidextract of digitalis shall correspond to 0.83 milligram of ouabain.

(Fluidextract jalap) One hundred cubic centimeters of the article yielded more than 7.5 grams, namely, not less than 13.4 grams of the resin of jalap, whereas the formulary provides that 100 cubic centimeters of fluidextract of jalap shall yield not more than 7.5 grams of the resin of jalap.

(Fluidextract nux vomica) One hundred cubic centimeters of the article yielded less than 2.37 grams, namely, not more than 1.72 grams of the alkaloids of nux vomica, whereas the formulary provides that 100 cubic centimeters of fluidextract of nux vomica shall yield not less than 2.37 grams of the alkaloids of nux vomica.

(Fluidextract stramonium) One hundred cubic centimeters of the article yielded more than 0.28 gram, namely, not less than 0.3476 gram of the alkaloids of stramonium, whereas the formulary provides that 100 cubic centimeters of

fluidextract of stramonium shall yield not more than 0.28 gram of the alkaloids of stramonium.

(Tincture ferric citro-chloride) The article contained less than 11.9 percent of alcohol by volume, namely, not more than 1.8 percent of alcohol by volume, whereas the formulary provides that tincture ferric citro-chloride shall contain not less than 11.9 percent of alcohol by volume.

(Elixir gentian and iron) One hundred cubic centimeters of the article contained less than 0.448 gram of iron, namely, not more than 0.393 gram of iron, whereas the formulary provides that tincture ferric citro-chloride, i. e., elixir gentian and iron chloride shall contain not less than 0.448 gram of iron.

(Elixir sodium salicylate compound) One thousand cubic centimeters of the article contained 146.3 grams of sodium salicylate and 0.4 gram of potassium iodide, whereas the formulary provides that elixir sodium salicylate compound shall contain not more than 80 grams of sodium salicylate and not less than 15 grams of potassium iodide per 1,000 cubic centimeters.

(Syrup hypophosphites compound) The article contained less than 35 grams, namely, not more than 24.58 grams, of calcium hypophosphite per 1,000 cubic centimeters, whereas the formulary provides that syrup hypophosphites compound shall contain 35 grams of calcium hypophosphite per 1,000 cubic centimeters.

(Syrup bromides) The article contained less than 80 grams, namely, not more than 69.3 grams of sodium bromide per 1,000 cubic centimeters, whereas the formulary provides that 1,000 cubic centimeters of syrup of bromides shall contain not less than 80 grams of sodium bromide.

Adulteration was alleged with respect to all products with the exception of the elixir sodium salicylate compound for the further reason that their strength and purity fell below the professed standard and quality under which they were sold in the following respects:

The fluidextract digitalis and fluidextract jalap were represented to conform to the standard laid down in the National Formulary, whereas they did not.

The fluidextract nux vomica was represented to conform to the National Formulary and to contain 2.5 percent alkaloids, whereas it did not conform to the formulary and contained less than 2.5 percent alkaloids.

The fluidextract stramonium was represented to conform to the standards laid down in the National Formulary and to contain 0.25 percent alkaloids, whereas it did not conform to the formulary and contained more than 0.25 percent alkaloids.

The tincture ferric citro-chloride was represented to contain 14 percent of alcohol, whereas it contained less than 14 percent of alcohol, namely, not more than 1.8 percent of alcohol.

The elixir gentian and iron was represented to contain 20 percent of alcohol and 48 minims of tincture of iron citro-chloride, whereas it contained less alcohol and tincture of iron citro-chloride than represented, namely, not more than 13.38 percent of alcohol and not more than 42.1 minims of tincture of iron citro-chloride.

The syrup hypophosphites compound was represented to conform to the standard laid down in the National Formulary and to contain in each fluid ounce 16 grains of calcium hypophosphite,  $\frac{3}{8}$  grain of quinine hypophosphite, and  $\frac{1}{8}$  grain of strychnine hypophosphite, whereas it did not conform to the formulary and each fluid ounce contained less than 16 grains of calcium hypophosphite, less than  $\frac{3}{8}$  grain of quinine hypophosphite, and less than  $\frac{1}{8}$  grain strychnine hypophosphite.

The syrup bromides was represented to conform to the standard laid down in the National Formulary and each fluid ounce was represented to contain 36 grains of sodium bromide, whereas it did not conform to the National Formulary and each fluid ounce contained less than 36 grains, namely, not more than 31.6 grains of sodium bromide.

Misbranding was alleged for the reason that the statements "Fluidextract Digitalis N. F.", "Fluidextract Jalap N. F.", "Fluidextract Nux Vomica N. F. \* \* \* Standard-2.5% Alkaloids", "Fluidextract Stramonium N. F. \* \* \* Standard-0.25% alkaloids", "Tincture Ferric Citro-Chloride \* \* \* Alcohol 14 per cent", "Elixir Gentian and Iron N. F. IV \* \* \* Each fluid ounce contains \* \* \* Tincture Iron Citro-Chloride 48 Mim \* \* \* Alcohol 20 percent", "Syrup Hypophosphites Compound N. F. Each fluid ounce contains \* \* \* Calcium Hypophos, 16 grs. \* \* \* Quinine Hypophos,  $\frac{3}{8}$  Grs.", and "Syrup Bromides N. F. Each fluidounce contains: \* \* \* Sodium Bromide, 36 Grs.", borne on the labels of the respective products were

false and misleading. Misbranding of the tincture ferric citro-chloride and the elixir gentian and iron was alleged for the further reason that they contained alcohol and the label of the packages failed to bear a statement of the quantity and proportion of the alcohol contained therein.

On July 30, 1934, a plea of guilty was entered on behalf of the defendant company, and the court imposed a fine of \$200.

M. L. WILSON, *Acting Secretary of Agriculture.*

**23227. Adulteration and misbranding of elixir pepsin, bismuth, and strychnine; belladonna solid extract; solid extract nux vomica; elixir tonga and salicylates; citrine ointment; ointment resorcin compound; tincture opium camphorated; powdered extract belladonna, and misbranding of pentabromides. U. S. v. The Wm. S. Merrell Co. Plea of guilty. Fine, \$170. (F. & D. no. 31322. Sample nos. 3780-A, 3795-A, 3796-A, 4103-A, 4142-A, 4143-A, 8571-A, 8655-A, 8656-A.)**

This case was based on interstate shipments of belladonna solid extract, solid extract nux vomica, elixir tonga and salicylates, citrine ointment, ointment resorcin compound, tincture opium camphorated, and powdered extract belladonna, products recognized in the United States Pharmacopoeia or the National Formulary, which fell below the standard laid down in those authorities, and in some instances contained therapeutic agents in amounts differing from those declared on the label. There was also included one lot of elixir pepsin, bismuth and strychnine that contained less bismuth and sodium tartrate than declared on the label, and one lot of pentabromides that contained the combined bromides of sodium, potassium, lithium, calcium and ammonium, greatly in excess of the amount declared.

On September 17, 1934, the United States attorney for the Southern District of Ohio, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Wm. S. Merrell Co., a corporation, Cincinnati, Ohio, alleging shipment by said company in violation of the Food and Drugs Act, on or about January 20 and April 13, 1932, from the State of Ohio into the State of New York, of quantities of powdered extract of belladonna and tincture opium camphorated, which were adulterated and misbranded; on or about March 14, 1932, from the State of Ohio into the State of Pennsylvania, of a quantity of pentabromides which were misbranded; and on or about June 30, 1932, from the State of Ohio into the States of Illinois and Kentucky, of quantities of elixir pepsin, bismuth and strychnine, belladonna solid extract, solid extract nux vomica, elixir tonga and salicylates, citrine ointment, ointment resorcin compound, which were adulterated and misbranded. The articles were labeled in part: "The Wm. S. Merrell Company, Cincinnati, Ohio."

The information charged adulteration of certain of the products in that they were sold under names recognized in the United States Pharmacopoeia or the National Formulary, and differed from the standard of strength, quality, and purity as determined by the tests laid down in the said authorities official at the time of investigation, in the following respects:

Belladonna solid extract yielded less than 1.18 percent, namely, not more than 0.70 percent of the alkaloids of belladonna leaves; whereas the pharmacopoeia provides that extract of belladonna shall yield not less than 1.18 percent of the alkaloids of belladonna leaves.

Solid extract nux vomica yielded less than 15.2 percent, namely, not more than 12.84 percent of the alkaloids of nux vomica; whereas the pharmacopoeia provides that extract of nux vomica shall yield not less than 15.2 percent of the alkaloids of nux vomica.

Tincture opium camphorated contained less than 0.4 gram, namely, not more than 0.317 gram, of anhydrous morphine per 1,000 cubic centimeters; whereas the pharmacopoeia provides that tincture camphorated opium shall contain not less than 0.4 gram of anhydrous morphine per 1,000 cubic centimeters.

Powdered extract belladonna yielded less than 1.18 percent, namely, not more than 0.83 percent of the alkaloids of belladonna leaves; whereas the pharmacopoeia provides that extract of belladonna shall yield not less than 1.18 percent of the alkaloids of belladonna leaves.

Elixir tonga and salicylates contained more than 70 grams, namely, not less than 77 grams of sodium salicylate per 1,000 cubic centimeters; whereas the National Formulary provides that elixir tonga and salicylates shall contain not more than 70 grams of sodium salicylate per 1,000 cubic centimeters.

Citrine ointment contained more than 7 grams, namely, not less than 8.07 grams of mercury for 100 grams of ointment; whereas the National Formulary